UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,353	05/04/2001	James M. Staddon	0623.0410001/EKS/BJD	1015

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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER
BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
2665	

DATE MAILED: 03/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/848,353	Staddon et al
Examiner	**Art Unit**
Michael Borin	1631

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-20 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Part III DETAILED ACTION

Claims 1-20 are currently pending.

It is noted that claims 1-19 are in improper "use" format. For purposes of this restriction requirement these claims will be viewed as method claims. Further, as the claims (except claims 6-8) do not specify the nature of agent, classification of the groups will be established upon selection of particular species.

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1,2, and 5,9-11 (in part), drawn to method of use of agent which promotes tyrosine dephosphorylation in making a medicament for reducing permeability of a physiological barrier.

II. Claim 12, drawn to method of use of agent which promotes tyrosine dephosphorylation in making a medicament for treating brain oedema.

III. Claim 13, drawn to method of use of agent which promotes tyrosine dephosphorylation in making a medicament for treating peripheral oedema.

IV. Claim 14, drawn to method of use of agent which promotes tyrosine dephosphorylation in making a medicament for blocking leukocyte entry.

V. Claim 15, drawn to method of use of agent which promotes tyrosine dephosphorylation in making a medicament for treating multiple sclerosis.

VI. Claim 16, drawn to method of use of agent which promotes tyrosine dephosphorylation in making a medicament for preventing cancer metastasis.

VII. Claim 19, drawn to method of use of agent which promotes tyrosine dephosphorylation in making a medicament for treating gastric ulcers.

VIII. Claims 3,4, 6-8, and 5,9-11 (in part) drawn to method of use of agent which promotes tyrosine phosphorylation in making a medicament for increasing permeability of a physiological barrier.

IX. Claim 17, drawn to method of use of agent which promotes tyrosine phosphorylation in making a medicament to be delivered to brain.

X. Claim 18, drawn to method of use of agent which promotes tyrosine phosphorylation in making a medicament for treating mucus accumulation.

XI. Claim 19, drawn to method of use of agent which promotes tyrosine phosphorylation in making a medicament for gastric ulcers.

XII Claim 20, drawn to a composition comprising a drug and an agent which promotes tyrosine phosphorylation.

Inventions I-VII and VIII-XI are patentably distinct as they are drawn to agents with opposite modes of action, tyrosine dephosphorylation and tyrosine phosphorylation, respectively.

Groups I-VII are drawn to independent and/or patentably distinct methods. The medicaments obtained by the respective methods have different effects and modes of use. The Groups are drawn to medicaments for treatment of patentably distinct disorder conditions which are not related to each other, have different mechanisms of development and etiology, and have different enablement requirements. The groups require different literature search and a reference teaching treatment of one disorder (e.g., oedema) will not teach treatment of any other disorder (e.g., cancer or multiple sclerosis).

Similarly, Groups VIII-X are drawn to independent and/or patentably distinct methods. The medicaments obtained by the respective methods have different effects

and modes of use. In addition, method of Group IX requires combination of drugs not required by methods of Groups VIII, X, XI.

The composition of Group XII is independent from the methods of Groups VIII-XI because it can be used in a materially different processes, e.g., regulation of *in vitro* cell growth.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art because of their recognized divergent subject matter, and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Species Requirement

If Groups I,VIII are elected, the following election of species is hereby required for the search purposes:

The claims of Group VIII are individually or dependently directed to a plurality of disclosed patentably distinct species of agents affecting tyrosine kinase phosphorylation, such as those disclosed in claims 6-8.

The claims of Group I, VIII are individually or dependently directed to a plurality of disclosed patentably distinct species of tyrosine phosphorylation regulating enzymes, such as those disclosed in claims 10-11.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied

by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Mr. Michael Woodward, can be reached at (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 19, 2003

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

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